REMARKS

By this Amendment, claim 10 is amended. Claims 11-18 remain in the application. Thus, claims 10-18 are active in the application. Reexamination and reconsideration of the application are respectfully requested.

Claim 10 has been amended in order to include limitations which were originally presented therein but which were inadvertently omitted in claim 10 as presented in the March 19, 2004 Amendment After Final.

In item 4 on page 2 of the Office Action, claims 10, 12 and 14-15 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Engleson et al. (U.S. 5,781,442) in view of Bloom et al. (U.S. 6,070,761). This rejection is respectfully traversed for the following reasons.

The present invention provides an apparatus for supporting injection mixing work that is to be conducted before dosing a plurality of injections to a patient. As is described in lines 8-11 on page 1 of the original specification and in paragraph [0002] of the substitute specification, a plurality of injections are commonly dosed to a patient in a medical facility. In order to ensure that the patients do not receive injections that are incompatible with each other or which may become incompatible with each other when given to a particular patient, the apparatus of the present invention supports injection mixing work before a plurality of injections are dosed to a patient by determining a mixing order of the injections. The apparatus of the present invention then displays the determined mixing order of the injections on a display in order to support a mixing operator in conducting mixing work of injections before the injections are dosed to a patient.

Claim 10 recites an apparatus for supporting injection mixing work to be conducted before dosing a plurality of injections to a patient. The apparatus of claim 10 comprises a memory which is operable to store data for supporting injection mixing work. The memory is operable to store a patient predictability data file for storing patient predictability data, an injection prescription data file for storing injection prescription data corresponding to the patient predictability data, and a combination related data file for storing combination related data corresponding to each injection of the injection prescription data and used for determining an

incompatibility for a mixing order when each injection of the injection prescription data is combined with another injection. The apparatus of new claim 10 further comprises a display operable to display the data stored in the memory, and a controller which is operable to determine, before the injections are dosed to a patient, a mixing order of the injections contained in the injection prescription data in accordance with the combination related data and to display the mixing order on the display.

Engleson et al. discloses a patient management system which is capable of monitoring, controlling and tracking the administration of care in a health care institution (see Column 2, lines 24-27). That is, the patient management system of Engleson et al. merely conducts a management when dosing injections to patients. The apparatus of the present invention, however, as described above, determines a mixing order of a plurality of injections before the injections are dosed to a patient, and displays the determined mixing order on a display in order to support a mixing operator in conducting mixing work of injections before the injections are dosed to a patient.

Nonetheless, despite this clear difference in both purpose and effect between Engleson et al. and the apparatus of the present invention as recited in claim 10, the Examiner is maintaining his reliance on the disclosure of Engleson et al. to reject claim 10.

Engleson et al. discloses a care management system 30 in which the management of the administration of care for patients is automated between a plurality of stations in a medical facility and/or a pharmacy. The care management system 30 is disclosed as allowing medical professionals such as nurses to monitor and regulate, in real-time, the administrations for patients. However, the care management system 30 is merely limited to monitoring or verifying "that medication is administered to the right patient, in the right dose, along the right route, and at the right time" where such monitoring is performed by the network of the care management system 30 (see column 8, lines11-13). In other words, the care management system 30 is merely a real-time verification that a patient receives the proper medications and/or treatment that were prescribed according to a physician's specific directions.

In order to ensure that patients are cared for according to a physician's orders, the care management system 30 includes a medical administration management module 110. With reference to Column 8, line 66 to Column 9, line 12 and Figure 9, the Examiner is again insisting that the administration management module 110 of Engleson et al. corresponds to the controller as recited in claim 10. The Examiner has again insisted, in item 5 on pages 2-3 of the Office Action, that Engleson et al. discloses a controller which is operable to determine a mixing order of the injections contained in the injection prescription data in accordance with the combination related data, and to display the determined mixing order on the display. To support this conclusion, the Examiner again refers to column 8, line 66 to column 9, line 12 and to figures 9 and 10 of Engleson et al. The Applicants respectfully disagree with this interpretation of Engleson et al. by the Examiner for the following reasons.

The medical administration management module 110 is capable of integrating medical order information, infusion pump monitoring and bar code technology so as to support the real-time verification and charting of medications being administered to a patient (see column 6, lines 54-58). In addition, the medical administration management module 110 is disclosed as creating and maintaining an online, real-time, patient-specific medication administration record (MAR) or an integrated medication administration record (IMAR) for each patient. In other words, the medical administration management module 110 is capable of storing and gathering all of the information generated for the proper care of a patient and disseminating such information over the network (see column 6, lines 58-65). For instance, the medical administration management module 110 is disclosed as recording the start time, duration and end time of an infusion to a patient (see column 8, lines 14-29), maintaining an online, real-time graphical medical administration record of each patient that includes past, present and future medications (see column 8, lines 30-38), and allowing nurses to perform online queries of a patient's MARs in order to assist the nurse to plan medication administration and to schedule the work load of dispensing the medication to a number of patients for which a nursing unit is responsible (see column 8, line 66 to column 9, line 16).

Accordingly, Engleson et al. merely discloses that the medical administration module 110 "assists" the nurse or other health care professional to efficiently deliver care to the patients by providing the nurse the ability to perform online queries of the patients MARs and by producing reports that are designed to "assist the nurse in planning medication administration and in scheduling the workload of dispensing the medication to the many patients for which a nursing unit is typically responsible" (see column 8, lines 66 to column 9, line 6). In other words, with reference to figure 9 of Engleson et al., the medical administration management module 110 merely provides a visual display of a patient's IMAR which indicates all of the medications that were prescribed for a patient, the times that the medications are to be given, and the amounts of each medications so as to "assist" the nurse in ensuring that each medication is given on the prescribed time and for the prescribed amounts. The IMAR of figure 9 is pre-generated and merely contains each of the medications that were prescribed for a particular patient, and the task list of figure 10 is merely a schedule of drug administration for a number of patients which "assists" the nurse to plan accordingly so as to "ensure that all medication is given promptly" (see column 9, lines 6-16). Accordingly, the medical administration management module 110 merely generates a visual display of a patient's MAR or IMAR to illustrate each of the prescribed medications, the times the medications are to be given, and the amounts of each medication for the patient.

The above-referenced portions of Engleson et al. merely disclose a care management system 30 in which a display indicates the status and schedule of each drug administration in order to assist the nurse in planning medication administrations and in scheduling the workload of dispensing the medication to the required patients.

The medical administration management module 110, however, does not determine a mixing order of the injections since the medical administration management module 110 merely allows the care management system 30 to monitor whether a proper administration or dosing of a prescription has been conducted and since the medications that are visually displayed on the display screen are not determined by the medical administration management module 110 but

are merely a reflection of either the order in which the medications are entered into the system or the order in which a physician prescribed the medications.

Accordingly, the care management system 30 of Engleson et al., together with the medical administration management module 110, is merely a system for ensuring that the proper medicine is delivered to the proper patient after the medicine is prescribed by a doctor and obtained from a pharmacy or hospital medicine storeroom. In other words, the care management system 30 of Engleson et al. is merely an integrated network system that assists nurses in ensuring that each patient receives the medicinal care that was prescribed by monitoring and checking the patient care for each patient in real-time.

Therefore, Engleson et al. does not disclose or suggest a controller which is operable to determine, before the injections are dosed to a patient, a mixing order of the injections contained in the injection prescription data in accordance with the combination related data, as recited in claim 10.

Furthermore, despite the Examiner's assertion to the contrary, Engleson et al. does not disclose or suggest a memory being operable to store a combination related data file for storing combination related data corresponding to each injection of the injection prescription data and used for determining an incompatibility or a mixing order when each injection of the injection prescription data is combined with another injection, as recited in claim 10. The Examiner supports his conclusion that Engleson et al. discloses the combination related data file and the combination related data of claim 10 by referring to Column 6, lines 54-58.

However, as described above, Column 6, lines 54-58 merely disclose that the medical administration management module 110 is capable of integrating medical order information, infusion pump monitoring and bar code technology so as to support the real-time verification and charting of medications being administered to a patient. Further, as described above, the care management system 30 of Engleson et al. is merely disclosed as displaying each prescription that is prescribed for a patient, and that the care management system 30 operates as a real-time check list for nurses to ensure that each patient is receiving his or her prescribed care. Accordingly, the "combination related data file" and "combination related data" which the Examiner interprets as

being disclosed in Engleson et al. is merely an integration of various data such as medical order information and infusion pump monitoring which is collected and displayed so as to support the real-time verification and charting of medications being administered to a patient. In other words, the so-called "combination related data file" of Engleson et al. is merely a collection of data relating to the medicinal care of a patient that is conveniently displayed on a single display device for the administering nurse. The "combination related data file" of Engleson et al., however, clearly is not used for determining an incompatibility or a mixing order when each injection of the injection prescription data is combined with another injection.

Accordingly, Engleson et al. clearly does not disclose or suggest a memory which is operable to store a combination related data file for storing combination related data corresponding to each injection of the injection prescription data and used for determining an incompatibility or a mixing order when each injection of the injection prescription data is combined with another injection, as recited in claim 10.

Therefore, Engleson et al. clearly does not disclose or suggest the combination related data file, the combination related data or the controller as recited in claim 10.

In item 5 on page 3 of the Office Action, the Examiner acknowledged that Engleson et al. does not disclose or suggest "determining an incompatibility or a mixing order when each injection of the injection prescription file is combined with another injection and that a mixing order is determined before the injections are dosed to a patient." To teach this feature, the Examiner cited Bloom et al. as disclosing a system which supports the delivery of intravenous drugs that includes determining an incompatibility or a mixing order when each injection of the injection prescription data is combined with another injection and that a mixing order is determined by the controller before the injections are dosed to a patient. Accordingly, the Examiner concluded that it would have been obvious to combine the disclosure of the Engleson et al. with the controller of Bloom et al. to result in the invention of claim 10.

Bloom et al. discloses an automated medication management system which automatically and mechanically conducts the admixture (including reconstruction and dilution) and delivery of intravenous drugs to patients by using a cassette 77 and a fluid delivery module 88 (see Column

15, lines 31-67 and Figures 7 and 8). The apparatus of the present invention, as recited in claim 10, does not conduct the actual mixing work of injections but instead determines a mixing order of a plurality of injections and displays the determined mixing order in order to provide support to a mixing operator to conduct the mixing work of injections.

Therefore, the system of Bloom et al. is not relevant to the apparatus of the present invention. Furthermore, it is not possible to incorporate the system of Bloom et al. which conducts the admixture of intravenous drugs into the system of Engleson et al. which conducts management of the administration of care to patients. Even if these two systems were combined together, however, such a combination would not result in the apparatus of claim 10 for supporting injection mixing work to be conducted before dosing a plurality of injections to a patient.

The Examiner relies on Column 33, line 45-59 to cure the deficiencies of Engleson et al. for failing to disclose or suggest the controller of claim 10. Column 33, line 45-59 of Bloom et al. discloses:

> [A]utomated medication management system 300 allows the clinician identify the drug and the diluent during setup via the bar code scanner or selection from a drop down menu or entry via other user interface. In one embodiment, the identified drug must match an item in the pharmaceutical database for the system to begin mixing and/or infusing. Once the match is made by the present invention, the recommended mixing and/or delivery parameters are displayed on the user interface for the clinician to review. The parameters can be changed by the clinician as long as the change conforms to the minimum and maximum recommendations set forth in the pharmaceutical database. If the change does not conform, the clinician is notified that the parameters are out of range. In one embodiment, administration of the medication will not be permitted to proceed unless a professional with the proper level of authorization allows the out of range delivery.

Accordingly, the above-referenced portion of Bloom et al. merely discloses that the recommended mixing and/or delivery parameters are displayed so that the clinician can change the parameters within the pharmaceutical database. This portion of Bloom et al., however, does not disclose or suggest a controller which is operable to determine, before the injections are dosed to a patient, a mixing order of the injections contained in the injection prescription data in

accordance with the combination related data and to display the determined mixing order on the display so that a mixing operator can easily conduct mixing work.

Therefore, similar to Engleson et al., Bloom et al. also does not disclose or suggest a controller operable to determine, before the injections are dosed to a patient, a mixing order of the injections contained in the injection prescription data in accordance with the combination related data, and to display the determined mixing order on the display, as recited in claim 10.

Furthermore, Bloom et al. also does not disclose or suggest a memory which is operable to store a combination related data file for storing combination related data corresponding to each injection of the injection prescription data and used for determining an incompatibility or a mixing order when each injection of the injection prescription data is combined with another injection.

Instead, Bloom et al. merely discloses that automated medication management system 300 cross checks the medication to be administered against data contained in one or more databases to provide a safeguard against administration of improper medications or at improper dosage levels. Bloom et al. discloses that a control and management module 304 "checks the intended medication against information in the one or more databases and enables delivery only after verification that the particular patient is to receive a prescribed drug in the correct amount, with the proper diluent if required, at the proper time" (see Column 8, lines 35-47).

Accordingly, Bloom et al. merely disclosing cross checking databases in order to ensure that the patient is or will actually be administered the prescribed medication. Bloom et al. discloses that this safety check can be performed at any time after the prescription is entered and, ideally, before the prescribed medication is administered (see Column 8, lines 48-53).

However, while the safety check of Bloom et al. seeks to ensure that the patient is actually administered the prescribe medication, the safety check does not employ combination related data file for storing combination related data corresponding to each injection of the injection prescription data and used for determining an incompatibility or a mixing order when each injection of the injection prescription data is combined with another injection.

Therefore, similar to Engleson et al., Bloom et al. also does not disclose or suggest a memory which is operable to store a combination related data file for storing combination related data corresponding to each injection of the injection prescription data and used for determining an incompatibility or a mixing order when each injection of the injection prescription data is combined with another injection, as recited in claim 10.

Accordingly, Bloom et al. clearly does not cure the deficiencies of Engleson et al. for failing to disclose or suggest each and every limitation of claim 10.

In item 19 on page 7 of the October 20, 2003 Office Action, the Examiner asserted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. The Examiner is again respectfully reminded that an obvious combination of references cannot result in disclosing each and every limitation of a claim when none of the references, either individually or in combination, disclose or suggest each and every limitation of the claim.

Therefore, since neither Engleson et al. nor Bloom et al. disclose or suggest, either individually or in combination, a controller operable to determine, before the injections are dosed to a patient, a mixing order of the injections contained in the injection prescription data in accordance with the combination related data, and to display the determined mixing order on the display, as recited in claim 10, the Applicants respectfully submit that claim 10 is clearly patentable over the combination of Engleson et al. and Bloom et al.

In item 10 on page 4 of the Office Action, claims 11 and 16 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Engleson et al. in view of Bloom et al. and further in view of Merki et al (U.S. 5,002,055). Further, in item 13 on page 5 of the Office Action, claims 13 and 17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Engleson et al. in view of Bloom et al. and further in view of Mayaud (U.S. 5,845,255).

For the following reasons, the Applicants respectfully submit that neither Merki et al. nor Mayaud, either individually or in combination, cure the deficiencies of Engleson et al. and Bloom et al. for failing to disclose or suggest each and every limitation of claim 10.

Merki et al. discloses a gastric pH sensor 1 for intraluminally measuring the H^+-ion activity of gastric juices. Merki et al. also discloses that the measured pH data resulting from the infusion of a primary medication are stored and compared with the reference values that are stored in a microprocessor. Merki et al. discloses that, during the infusion of a prescribed medication, another medication can be combined with the prescribed medication when the measured pH values are deemed to be unacceptable so as to achieve the desired therapy objective. However, combining the primary medication with another medication is only performed when the measured pH values indicate a deviation of the therapy objective after dosing of the primary medication is performed, which is clearly unrelated to supporting injection mixing work that is to be conducted before dosing a plurality of injections to a patient, as recited in claim 10.

Accordingly, the Applicants respectfully submit that Merki et al. clearly does not cure the deficiencies of Engleson et al. and Bloom et al. for failing to disclose or suggest an apparatus for supporting injection mixing work to be conducted before dosing a plurality of injections to a patient since Merki et al. also does not disclose or suggest a controller which is operable to determine, before the injections are dosed to a patient, a mixing order of the injections contained in the injection prescription data in accordance with the combination related data, as recited in claim 10. Furthermore, Merki et al. does not disclose or suggest a memory which is operable to store the combination related data file for storing combination related data corresponding to each injection of the injection prescription data and which is used for determining an incompatibility or a mixing order when each injection of the injection mixing data is combined with another injection, as recited in claim 10.

Therefore, Merki et al. clearly does not cure the deficiencies of Engleson et al. and Bloom et al. since Merki et al. also fails to disclose or suggest the memory and the controller as recited in claim 10.

Mayaud discloses reviewing for contraindications of drugs and for special precautions, such as a patient's allergies, for a drug's use. However, Mayaud merely discloses a prescription management system for avoiding possible drug-to-drug interactions with other drugs that have

been previously prescribed. (see column 31, lines 19-24 and 33-39). That is, Mayaud merely discloses a screening or reviewing system for avoiding possible unintended adverse outcomes between a previously prescribed medication and a possible new medication that is to be prescribed to a patient. That is, Mayaud merely discloses a screening process for avoiding possible adverse outcomes between previously prescribed medications and a possible new medication. Mayaud, however, does not disclose or suggest an apparatus for supporting injection mixing work to be conducted before dosing a plurality of injections to a patient which comprises a controller operable to determine, before the injections are dosed to a patient, a mixing order of the injections contained in the injection prescription data in accordance with the combination related data, as recited in claim 10.

Furthermore, Mayaud does not disclose or suggest an apparatus for supporting injection mixing work to be conducted before dosing a plurality of injections to a patient having a memory which is operable to store a combination related data file for storing combination related data which corresponds to each injection of the injection prescription and which is used for determining an incompatibility or a mixing order when each injection of the injection data is combined with another injection, as recited in claim 10.

Accordingly, Mayaud clearly does not cure the deficiencies of Engleson et al., Bloom et al. and Merki et al. for failing to disclose or suggest the memory or the controller of claim 10.

Therefore, no obvious combination of Engleson et al., Bloom et al., Merki et al. and Mayaud would result in the invention of claim 10 since Engleson et al., Bloom et al., Merki et al. and Mayaud, either individually or in combination, clearly fail to disclose or suggest the controller of claim 10.

Accordingly, claim 10 is clearly patentable over Engleson et al., Bloom et al., Merki et al. and Mayaud.

Furthermore, it is submitted that the clear distinctions discussed above are such that a person having ordinary skill in the art at the time the invention was made would not have been motivated to modify Engleson et al., Bloom et al., Merki et al. and Mayaud in such a manner as to result in, or otherwise render obvious, the present invention as recited in claim 10. Therefore,

it is submitted that claim 10, as well as claims 11-18 which depend therefrom, are clearly allowable over the prior art as applied by the Examiner.

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is clearly in condition for allowance. An early notice thereof is respectfully solicited.

If, after reviewing this Amendment, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, it is respectfully requested that the Examiner contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

Hiroyuki YUYAMA et al.

By: Jonathan R. Bowser

Jonathan R. Bowser
Registration No. 54,574
Attorney for Applicants

JRB/ck
Washington, D.C. 20006-1021
Telephone (202) 721-8200
Facsimile (202) 721-8250
September 30, 2004